FEB - 8 2001

K003586

VII. 510(k) SUMMARY

In response to the requirements addressed by the Safe Medical Devices Act (SMDA) of 1990, a summary follows with the safety and effectiveness information upon which the substantial equivalence determination is based.

510(k) SUMMARY
FOR
Focus® DAILIES® (nefilcon A) One-Day Contact Lenses

1. **Submitter Information**

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097
Contact Person: Steven Dowdley (Regulatory Specialist)
Telephone No. 678-415-3897

2. **Device Name**

Classification Name: Soft (hydrophilic) Contact Lens
Proprietary Name: Focus® DAILIES® (nefilcon A) One-Day Contact Lenses

3. **Predicate Devices**

The predicate device for this submission is the Focus® DAILIES® (nefilcon A) One-Day Contact Lens cleared under K963487.

4. **Description of Device**

The device description has from the device that was cleared under K963487.

The Focus® DAILIES® (nefilcon A) One-Day Contact Lenses are a daily wear soft contact lens intended for single use daily disposable wear. The lens material is 69% water and 31% nelfilcon A polymer (polyvinyl alcohol partially acetalized with N-formylmethyl acrylamide).

The Focus® DAILIES® (nefilcon A) One-Day Contact Lenses are available in a spherical lens design of the following dimensions:

- Chord Diameter: 13.8
- Center Thickness: 0.09 to 0.17 mm (0.10 at -3.00)
- Base Curve: 8.6 mm
- Powers: +4.00D to -6.00D (0.25D steps), -6.50D to -8.00D (0.50D steps)

A clear lens has the following properties:

- Specific gravity: 1.06
- Refractive index: 1.38 (hydrated)
- Light transmittance: ≥ 97%
- Water content : 69% by weight in normal saline

Lenses are supplied sterile in foil sealed blister packs containing isotonic buffered saline solution. The packaging components have tested non-toxic when evaluated in *in-vitro* and *in-vivo* laboratory studies, and packaged lenses are effectively steam sterilized in a validated autoclave. Blister packs are labeled with the lens parameters, lot number and product expiration date. The expiration date has been established through stability studies that have assessed the chemical stability of the lens and package integrity (ability to maintain sterility). Stability study data currently

supports a thirty (30) month shelf-life for the Focus® DAILIES® (nefilcon A) One-Day Contact Lenses in foil packaging. Shelf-life studies are ongoing to determine extension of expiration dating.

5. Indications for Use:

Focus DAILIES® (nelfilcon A) ONE-DAY CONTACT LENSES are indicated for daily wear for the optical correction of refractive ametropia in not-aphakic persons with non-diseased eyes who are myopic or hyperopic and may have minimal astigmatism that does not interfere with visual acuity.

Focus DAILIES® ONE-DAY CONTACT LENSES are to be prescribed for single use Daily Disposable Wear. Focus DAILIES® lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

6. Reason for 510(k) Submission

The reason for this 510(k) is to revise the package insert for the Focus® DAILIES® (nefilcon A) One-Day Contact Lenses to include the following statement::

A one-month subjective trial of contact lens wearers with a history of seasonal allergic conjunctivitis was conducted during a month of expected high pollen count in various US cities. Information was collected about allergy-related symptoms, wear-time and comfort during lens wear.

Study results found that these contact lens wearers experienced fewer days of burning and redness when wearing Focus DAILIES as compared to a new pair of their usual lenses. The effects of allergy medications that may have been used during the study were not assessed.

7. Non-Clinical Studies

Non–clinical studies were not conducted on the lens or lens material because there were not changes to the lenses.

8. Clinical Studies

The primary objective of the clinical study was to demonstrate that patients with seasonal allergic conjunctivitis have increased daily average wearing time and / or decreased subjective symptoms when wearing DAILIES as compared to their habitual > 2 weekly replacement daily wear soft contact lenses. This study was a prospective, parallel group study in which subjects were dispensed to wear either DAILIES or their habitual soft contact lenses for 1 month during a period when seasonal pollens were expected to be near their peak.

Consistent statistically significant benefits for DAILIES for the symptoms of burning, redness, and the SAC symptom sum were found when all subjects in this study were analyzed and among all subsets of the sample. A statistically significant benefit for DAILIES for the symptom of watering was found in the subsets of subjects who reported a pre-study history of always experiencing one or more of the major symptoms of SAC.

The results revealed that contact lens wearers who suffer from SAC may experience relief from some symptoms during allergy season by wearing DAILIES as compared to lenses that are replaced on cycles of 2 or more weeks.

9. Substantial Equivalence

The Focus® DAILIES® (nefilcon A) One-Day Contact Lens with the modified labeling is substantially equivalent to the currently marketed Focus® DAILIES® (nefilcon A) One-Day Contact Lens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2001

Mr. Steven Dowdley, R.A.C.
Regulatory Specialist
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, GA 30097

Re: K003586
Trade Name: Focus Dailies® (nelfilcon A) One-Day Contact Lenses
Regulatory Class: II
Product Code: 86 MVN, LPL
Dated: November 15, 2000
Received: November 20, 2000

Dear Mr. Dowdley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

PART III: INDICATIONS FOR USE STATEMENT

510(k) Number: *This is a new 510 (k) Notification. (~~number to be assigned~~)* K003586

Device Name: **Focus® DAILIES® (nelfilcon A) ONE-DAY CONTACT LENSES**

Indications for Use:

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Focus DAILIES® ONE-DAY CONTACT LENSES are to be prescribed for single use Daily Disposable Wear. Focus DAILIES® lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ☒ or Over-the-Counter: ☐

Division Sign-Off)
ision of Ophthalmic Devices
) Number K003586